UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP. Plaintiff/Counter Defendant v. BLUEWILLOW BIOLOGICS, INC. Defendant/Counter-Claimants	Case No. 2:21-cv-10312 HONORABLE STEPHEN J. MURPHY III

JOINT DISCOVERY PLAN

A. A Rule 16 Scheduling Conference is scheduled for November 3, 2021 at 10:00 AM. Appearing for the parties as counsel will be:

For the Plaintiff/Counter-Defendant: Stanley H. Kremen

For the Defendant/Counter-Claimant: Liane M. Peterson

1) **Jurisdiction:**

a) **Plaintiff's Position:**
The subject matter jurisdiction of this Court arises under 28 U.S.C. § 1331 concerning a federal question, the Patent Laws of the United States, 28 U.S.C. §§ 1338(a), (b), and 35 U.S.C. § 271. This is stated plainly in the complaint.

b) **Defendant's Position:**
The subject matter jurisdiction of this Court arises under 28 U.S.C. § 1331 concerning a federal question, the Patent Laws of the United States, 28 U.S.C. § 1338(a), and 28 U.S.C. §§ 2201 and 2202.

2) **Jury or Non-Jury:** The parties agree that this case is to be tried before a jury as trier of fact and before the Court as trier of law.

3) **Statement of the Case:**

a) **Plaintiff's Position:**
Plaintiff alleges that Defendant manufactured and sold products that infringe Plaintiff's U.S. Patent No. 8,163,802, and continues to develop products that infringe said patent.

b) **Defendant's Position:**
Plaintiff's complaint asserts that Defendant manufactured and sold a single product, NanoBio Protect®, which infringed U.S. Patent No. 8,163,802. Defendant denies infringement and asserts that the patent is invalid. Defendant counterclaimed requesting a declaratory judgment that said patent is invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112. Defendant also disputes whether the Court has jurisdiction to hear any claims of infringement with respect to its vaccine products under development for the reasons provided in section 15 below.

4) **Pendant State Claims:** There are no state claims, and the parties do not assert supplemental jurisdiction.

5) **Joinder of Parties and Amendment of Pleadings;** The parties expect to file all motions for joinder of parties to this action and to file all motions to amend the pleadings by April 30, 2022.

6) **Disclosures and Exchanges:** The parties are unable to agree on voluntary production at this time. However, the parties agree to discuss among themselves what initial disclosures will be provided by each so as to facilitate early resolution by settlement.

7) **Discovery:** The parties believe that all discovery procedures can be completed by September 30, 2022. The parties recommend the following discovery plan, and acknowledge that if the Court believes that discovery motions have been filed unnecessarily, in bad faith, or for vexatious or tactical reasons, the Court may appoint a Discovery Master to shift the costs of disposing of these motions from the Court to the parties:

Discovery Begins:	11/08/2021
Initial Disclosures Due:	12/13/2021
Witness List Disclosures Due:	03/20/2022
Close of Fact Discovery:	04/01/2022
Opening Expert Reports Due:	05/16/2022
Responsive Expert Reports Due:	07/01/2022
Reply Expert Reports Due:	08/15/2022
Expert Discovery Ends:	09/30/2022
Dispositive Motions Due:	10/28/2022

a) **Defendant's Position:**
Fact depositions are limited to 5 per side, absent a showing of good cause for a need for further depositions. Depositions are limited to no more than 7 hours in duration.

Requests for admission are limited to 25 per side.

b) **Plaintiff's Position:**
Until fact witnesses are identified along with the substance of their knowledge, limiting the number of depositions is unreasonable.

Further, Plaintiffs do not agree to limit the number of requests for admission.

8) **Disclosure / Discovery of Electronically Stored Information:** The parties have discussed the production of electronically stored information and suggest that such information be handled as follows:

The parties agree that there will be no e-mail discovery, and no production of electronically stored information from backup systems or other inaccessible sources, except for a showing of good cause. The parties will continue to discuss other reasonable limitations on the production of electronically stored information.

9) **Assertion of Claims of Privilege or Work-Product Immunity After Production:**

The parties agree that the inadvertent production of any documents or other material protected by the attorney-client privilege, work product doctrine, common interest doctrine, or any other privilege or immunity shall not be deemed a waiver of any claim of privilege or protection. If such material is inadvertently produced, the producing party shall promptly provide notice to the receiving party that the material be promptly returned or destroyed. The parties will consider additional procedures to follow for handling such inadvertent procedure in an appropriate protective order.

10) **Motions:**

The parties acknowledge that E.D. Mich. LR 7.1 requires a moving party to ascertain whether any motion will be opposed. All motions shall affirmatively state the efforts of the moving party to comply with the obligation created by Rule 7.1. All nondispositive motions shall be accompanied by a certificate setting forth in detail the efforts of the moving party to comply with the obligation created by Rule 7.1. All discovery motions shall be accompanied by a certificate and any relevant documentation or correspondence detailing the movant's attempts to seek resolution of the discovery dispute before filing the motion.

The following motions, including dispositive motions, are contemplated by each party:

Markman/Claim Construction briefing by both parties (to the extent there are any disputed claim terms requiring construction by the Court), including a Joint Claim Construction Chart

Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 8,163,802

The parties also contemplate filing additional Motions for Summary Judgment prior to trial

11) **Alternative Dispute Resolution:** The parties acknowledge that the Court reserves the right under Local Rule 16 to order alternative dispute resolution, and recommend that this case be submitted to the following method(s) of alternative dispute resolution:

a) **Plaintiff's Position:**
The parties already held two settlement negotiation sessions without arrival at a settlement. Plaintiff is not opposed to mediation efforts, with the mediators to be jointly chosen.

b) **Defendant's Position:**
The parties held two settlement meetings but were unable to reach agreement. Given the nature of the dispute and the amount in controversy, Defendant respectfully submits that this matter is appropriate for early alternative dispute resolution procedures, prior to the parties engaging in fact discovery, with the exception of limited discovery to facilitate settlement (sales records of NanoBio Protect®, correspondence with FDA regarding withdrawal of NanoBio Protect® from U.S. market, and license/settlement agreements related to U.S. Patent No. 8,163,802 and its related family members). In view of the above and Defendant's statement below regarding prospects of settlement, Defendant's preferred method of alternative dispute resolution is a settlement conference (E.D. Mich. LR 16.6) with persons having settlement authority on behalf of the parties in attendance.

12) **Length of Trial:** Counsel have conferred and were unable to reach agreement on an estimate for the length of trial.

a) **Plaintiff's Position:**
Plaintiff estimates the trial will last approximately 28 days total, lasting from 8:30 a.m. to 2:00 p.m. each day, allocated as follows:

14 days for Plaintiff's case
14 days for Defendant's case

b) **Defendant's Position:**
Defendant estimates that the trial should be completed in no more than 8 days total, lasting from 8:30 a.m. to 2:00 p.m. each day, allocated as follows:

4 days for Plaintiff's case
4 days for Defendant's case

13) **Prospects of Settlement:**
The status of settlement negotiations is:

The parties held two settlement meetings, which were attended by outside counsel and the respective CEOs of each party. The parties were unable to reach agreement on how to resolve the pending dispute.

a) **Defendant's Statement on Settlement:**
The only accused product at issue in this matter, NanoBio Protect®, was sold by Defendant for approximately one year, with limited sales. The accused product was withdrawn from the U.S. market at the instruction of the U.S. Food and Drug Administration ("FDA") as of May 2021 and Defendant has no plans to manufacture or sell the product in the future. Because the total amount in controversy is limited, Defendant respectfully submits that this matter should be set for a settlement conference pursuant to LR 16.6, with persons having settlement authority on behalf of the parties in attendance. Based on the prior settlement discussions between the parties, Defendant believes that the Court's assistance will be helpful to the parties in facilitating a prompt settlement of this matter, particularly in view of the amount in controversy and scope of the pending dispute. In view of the above, Defendant respectfully submits that conducting an early settlement conference pursuant to LR 16.6, before discovery proceeds (subject to the exceptions noted in section 11 above), will aid in expediting the disposition of the case prior to engaging in extensive discovery and other pretrial activities.

Defendant also disputes whether the Court has jurisdiction to hear any claims of infringement with respect to the vaccine products under development for the reasons provided in section 15. Thus, there should be no discovery on the vaccine products under development at any stage of this case, let alone prior to ADR proceedings, as such matters are not relevant to any claim or defense, and are not proportional to the needs of the case.

b) **Plaintiff's Response:**
Plaintiff is not opposed to mediation efforts, with the mediator to be jointly chosen. However, before settlement efforts can continue, discovery should be exchanged between the parties so that a mediator as well as the parties may understand the issues at hand. No settlement is possible without such an understanding. While it is true that the only accused product at issue in this matter at this time is NanoBio Protect®,

according to Plaintiff's information and belief, Defendant is continuing to develop products that infringe upon Plaintiff's U.S. Patent No. 8,163,802. Nevertheless, Plaintiff did not amend its complaint to include products under current development by Defendant due to a lack of precise knowledge of the ingredients and composition of these products and because these products were not tested to determine infringement of the patent claims with certainty. Discovery is needed before an amended complaint can be filed that alleges infringement by these products. Based upon information obtained from Defendant's publications, Plaintiff's expert indicated that these products probably infringe the claims of Plaintiff's patent.

Initiation of mediated settlement negotiations between the parties is likely to impact the discovery schedule in Section 12 *supra*.

14) **Electronic Document Filing System:** Counsel acknowledges that Local Rule 5.1 requires that attorneys file and serve all documents electronically, by means of the Court's CM/ECF system.

15) **Other:**

a) **Defendant's Statement:**

In addition to Defendant BlueWillow's position on settlement as described above in sections 11 and 13, Defendant raises two additional issues concerning prompt resolution of this dispute in view of the nature of the claims and the amount in controversy.

First, while BlueWillow believes that the parties should be able to promptly settle the matter with the Court's assistance, if that is not possible, BlueWillow respectfully submits that the matter can be resolved expeditiously on summary judgment directed to invalidity of the asserted patent.

Second, although Plaintiff's complaint accuses only a single product of infringement, NanoBio Protect®, Plaintiff has indicated that it intends to seek discovery related to BlueWillow's proposed intranasal vaccine products currently under development for the purpose of amending its complaint. BlueWillow's developmental vaccine products are primarily in the early pre-clinical stage, with some limited initial phase I clinical studies, all for the purpose of ultimately submitting an application to FDA for approval for commercial marketing in the future. They are not yet approved by the FDA or the subject of an application for FDA approval for commercial marketing. Thus, all ongoing development work by BlueWillow in connection with its proposed intranasal vaccine products is subject to the safe harbor of 35 U.S.C. § 271(e)(1) and the Court would not have jurisdiction to hear any claims of patent infringement on that basis. 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related

to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."); *Merck v. Integra*, 545 U.S. 193 (2005) (Section 271(e)(1) "exempt[s] from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs") (emphasis in original). Nor is the ongoing development work appropriately the subject of discovery in this matter for the same reasons stated herein. As Plaintiff has indicated that it intends to seek discovery on these developmental vaccine products for the purpose of amending its complaint, Defendant BlueWillow expects that this issue may require early Court intervention and resolution.

b) **Plaintiff's Response:**

First, Plaintiff asserts that the issue of invalidity of Plaintiff's patent should be resolved by the Court according to the U.S. Supreme Court decision in *Markman v. Westview Instruments*, 517 U.S. 370 (1996). Plaintiff also asserts that in Section 10 (*supra*), both parties agree that Markman claim construction briefs and patent validity summary judgment briefs should be submitted to the Court. However, Defendant appears to propose that the Court should proceed directly to the issue of patent validity and to suspend discovery efforts until that issue would be resolved. Doing so would delay the entire process should Defendant's allegations of patent invalidity fail. Discovery should continue according to the proposed schedule, and time should be afforded to both parties for Markman briefing and a possible Markman hearing.

Second, Defendant's assertion of the safe harbor of 35 U.S.C. § 271(e)(1) is an affirmative defense, and Defendant has the burden of establishing it. Plaintiff is entitled to discovery to test the allegations of Defendant regarding this defense. *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F.Supp.2d 1278, 1286-88 (S.D. Fla. 2005). The Hatch-Waxman Act provides that certain acts of drug producing entities may constitute acts of infringement. Further, Hatch-Waxman allows certain court-ordered remedies for patent owners. Plaintiff's discovery should proceed simultaneously along two paths: 1) whether Defendant's vaccine products potentially infringe Plaintiff's patent; and 2) for each potentially infringing product, does the safe harbor of 35 U.S.C. § 271(e)(1) apply. The first path addresses the products themselves, while the second path addresses the activities of Defendant.

Dated: October 28, 2021

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